Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: 2013/003

Scientific title of trial: Effects of early versus delayed umbilical cord clamping during antepartum lower segment caesarean section on placental delivery and post operative haemorrhage: a randomized controlled trial

Date of commencement (enrolment of first participant): 21st January 2013

Progression: 6 months \square 1 year \square 2 years \square 3 years \square

At completion $X\square$

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: pending/ recruiting/ recruitment complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 288

Number recruited and randomized: 156

Number allocated to each intervention/arm: 52

Losses/exclusions after randomization: Three cases in the 120 – 135 second, delayed cord clamping group. An intention to treat analysis was carried out including these three cases

3. Trial output

Summary of Interim/Final data (if available):

Delayed cord clamping (DCC) during antepartum caesarean section is feasible and safe. Although the mean duration for placental delivery was increased, DCC was not associated with increased post operative blood loss, occurrence of post partum haemorrhage or retained placentae

Presentations of results at scientific meetings:

This work was presented as a free oral communication at the FIGO-SAFOG-SLCOG Conference held in Colombo in October / November 2014 and published as an abstract in the Sri Lanka Journal of Obstetrics & Gynaecology 2014;36(Suppl 1): FC 4.5, Pg 14.

(Please attach a scanned copy or link to abstract)

Publications: A full paper has been submitted to the Ceylon Medical Journal for consideration of publication

(Please attach a scanned copy or link to paper)

Professor Malik Goonewardene

Name and signature of Responsible Registrant/

Name and signature of Responsible Registrant/ Date: 23.08.2016